



UNITED STATES PATENT AND TRADEMARK OFFICE

N.1/C

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,754	03/19/2001	Christopher Schuler	GC-425	8075

7590 05/12/2003

Sheldon H. Parker
Suite 300
300 Preston Avenue
Charlottesville, VA 22902

EXAMINER

MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 05/12/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/811,754

Applicant(s)

ED SCHULER, CHRISTOPHER

Examiner

Jennifer J Maynard

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 3763

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karageozian (WO 00/66139) in view of Knepper et al. (Invest Ophthalmol Vis Sci 1984), and further in view of Yasuyuki et al. (US 3,728,223 A).

Karageozian discloses a formulation of an injectable thimerosal-free, lyophilized hyaluronidase preparation which can be packaged for subsequent reconstitution prior to use, in balanced salt solution or sterile isotonic saline solution, which effectively produces reorganization of corneal collagen to rehabilitate irregularities and improve refractive errors that result from corneal surgeries.

Karageozian fails to disclose a method utilizing a hyaluronidase derived from *Streptomyces* for intraocular therapy to treat a variety of ophthalmological conditions.

Knepper et al. disclose a method of infusing a hyaluronidase derived from *Streptomyces* into a rabbit's eye to effectively decrease aqueous outflow resistance.

Karageozian in view of Knepper et al. fail to teach utilizing a hyaluronidase derived from *Streptomyces hyalurolyticus* which is characterized as being essentially free of contaminating protease and has a hyaluronidase activity of at least about 10 TRU.

Art Unit: 3763

Yasuyuki et al. disclose a process of producing and purifying a clinically stable hyaluronidase from *Streptomyces hyalurolyticus*.

Thus it would have been obvious to one having ordinary skill in the art to have modified Karageozian's method by utilizing a *Streptomyces* derived hyaluronidase because Knepper et al.'s study showed that *Streptomyces* hyaluronidase was more effective than testicular derived hyaluronidase in decreasing outflow resistance in the eye. Further it would have been obvious to one having ordinary skill in the art to have utilized a purified form of hyaluronidase derived from *Streptomyces hyalurolyticus* taught by Yasuyuki et al., as it was known to be more stable and more specific, as well as being biocompatible, non-toxic and therapeutic at certain dosage levels.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karageozian (WO 00/66139) in view of Knepper et al. (Invest Ophthalmol Vis Sci 1984), and further in view of Yasuyuki et al. (US 3,728,223 A), and further in view of Karageozian et al. (US 5,866,120 A).

Karageozian in view of Knepper et al. and further in view of Yasuyuki et al. fail to disclose utilizing hyaluronidase to clear hemorrhagic blood from the vitreous humor.

Karageozian et al. discloses the use of hyaluronidase to accelerate the clearance of hemorrhagic blood from the vitreous humor.

It would have been obvious to one having ordinary skill in the art to have modified the method taught by Karageozian in view of Knepper et al. and further in view of Yasuyuki et al., by utilizing hyaluronidase to clear hemorrhagic blood from the vitreous humor as disclosed by Karageozian et al., as hyaluronidase was shown to be effective in accelerating the clearance of hemorrhagic blood from the vitreous body of the eye.

Art Unit: 3763

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karageozian (WO 00/66139) in view of Knepper et al. (Invest Ophthalmol Vis Sci 1984), and further in view of Yasuyuki et al. (US 3,728,223 A), and further in view of Harris et al. (US 5,626,865 A).

Karageozian in view of Knepper et al. and further in view of Yasuyuki et al. fail to disclose utilizing hyaluronidase to soften the cornea of an eye.

Harris et al. discloses the use of hyaluronidase in an amount sufficient to cause corneal softening.

It would have been obvious to one having ordinary skill in the art to have modified the method taught by Karageozian in view of Knepper et al. and further in view of Yasuyuki et al., by utilizing hyaluronidase to soften the cornea of an eye as disclosed by Harris et al., as hyaluronidase was shown to be effective in softening the cornea of an eye.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karageozian (WO 00/66139) in view of Knepper et al. (Invest Ophthalmol Vis Sci 1984), and further in view of Yasuyuki et al. (US 3,728,223 A), and further in view of Straus (US 4,759,746 A).

Karageozian in view of Knepper et al. and further in view of Yasuyuki et al. fail to disclose utilizing hyaluronidase to enhance spreading of local anesthesia through ocular tissue.

Straus discloses intraocularly injecting a local anesthetic mixture, such as 15 cc of 0.75% bupivacaine, 5 cc of 4% lidocaine HCl and 1 cc of hyaluronidase, Column 4, lines 62-65.

It would have been obvious to one having ordinary skill in the art to have modified the method taught by Karageozian in view of Knepper et al. and further in view of Yasuyuki et al., by utilizing hyaluronidase to spread local anesthesia through ocular tissue as disclosed by Straus,

Art Unit: 3763

as hyaluronidase was known to be effective in enhancing the spread of local anesthesia through ocular tissue.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karageozian (WO 00/66139) in view of Knepper et al. (Invest Ophthalmol Vis Sci 1984), and further in view of Yasuyuki et al. (US 3,728,223 A), and further in view of Fedorov et al. (US 6,037,144 A).

Karageozian in view of Knepper et al. and further in view of Yasuyuki et al. fail to disclose utilizing hyaluronidase to isolate collagen to produce contact lenses.

Fedorov et al. disclose a method of using hyaluronidase for preparing artificial lenses.

It would have been obvious to one having ordinary skill in the art to have modified the method taught by Karageozian in view of Knepper et al. and further in view of Yasuyuki et al., by utilizing hyaluronidase to make artificial lenses as disclosed by Fedorov et al., as hyaluronidase was shown to be effective in isolating collagen from cattle basal membranes to form a collagen substrate utilized to manufacture contact lenses.

Response to Arguments

Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Art Unit: 3763

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard
May 5, 2003


GLENN K. DAWSON
PRIMARY EXAMINER